

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. Claim 16 has been amended, claims 9-11, 62 and 63 have been canceled, and new claims 65-68 have been added in the amendment filed May 9, 2011. Following the amendment, claims **1-3**, **13-16**, and **64-68** are pending and under examination in the current office action.

### ***Withdrawn Rejections***

2. Any objection or rejection of record pertaining to claims 9-11, 62 or 63 is rendered moot on account of Applicant's cancellation of said claims.

3. The objection warning of claim 16, for being a substantial duplicate of another claim, is withdrawn in view of Applicant's amendment to the claim.

4. The rejection of claim 16 under 35 U.S.C. 102(e) as being anticipated by US 2008/0090770 by Belmares, set forth at paragraph 11 of the previous office action, is withdrawn in view of Applicant's amendment to the claim. Claim 9 now depends from claim 2, which is not subject to the rejection.

5. The rejection of claims 1-3, 13-16 and 64 under 35 U.S.C. 102(e) as being anticipated by Gazit, set forth at paragraph 12 of the previous office action, is withdrawn in view of Applicant's arguments and upon further consideration of the reference.

Although larger peptides comprising the tripeptide ANF are disclosed, there is no explicit or implicit teaching to reasonably guide the artisan to a tripeptide consisting of ANF.

### ***Maintained Rejections***

#### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-3, 13-16 and 64-68 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 12/905,773. The rejection of claims 1-3, 13-16 and 64 is maintained for reasons of record and is further applied to new claims 65-68.

In the response filed May 9, 2011, Applicant states that he will make any required terminal disclaimer in patent application number 12/905,733 if and as required, at the appropriate time.

Accordingly, the provisional rejection of present claims 1-3, 13-16 and 64-68 is held in abeyance.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1 and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2008/0090770 A1 by Belmares et al. The rejection is maintained for reasons of record and as discussed below.

### ***Response to Arguments***

10. In the response filed May 9, 2011, Applicant argues that Belmares does not teach peptides related to amyloid inhibition, but rather peptides that may be utilized in the various cancer chemotherapy treatments. According to Applicant, Belmares only shows a 7-mer peptide as being effective for their purposes. Applicant asserts that Belmares does not disclose an “isolated” trimer or claim an isolated trimer with utility. Further, Applicant argues that the Belmares reference is not enabled for trimers, and that the genus of peptides is very large and there is no motivation or explicit teachings of the trimers of the present invention in the Belmares reference.

11. Applicant’s arguments have been fully considered but are not persuasive. Contrary to Applicant’s assertions, Belmares explicitly discloses the trimer peptide ANL (SEQ ID NO: 20) at paragraph 0073, which peptide is disclosed by Belmares as being useful in therapeutic applications, such as being comprised in a pharmaceutical composition. This peptide meets the structural limitations of the presently claimed peptide “ANX”, wherein X is any amino acid except cysteine. Therefore, as noted previously, the ANL peptide taught by Belmares would be expected to inherently possess antifibrillogenic activity as instantly claimed.

Regarding the alleged enablement of the Belmares disclosure, it is noted that MPEP § 2123(I) states “The use of patents as references is not limited to what the

patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain.” *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Hence, even non-preferred embodiments or embodiments not specifically used in the working examples are available for the purpose of applying prior art.

Further, because this a rejection under 35 U.S.C. 102 and the reference is anticipatory, Belmares does not need to provide motivation to use the ANL peptide for inhibiting amyloidosis and/or for cytoprotection as intended by the present claims. These are intended uses of the claimed peptide, and do not serve to structurally distinguish it from the prior art peptide of Belmares. A chemical composition and its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)), as are their processes and yields (*In re Von Schickh*, 362 F.2d 821, 150 USPQ 300 (CCPA 1966)). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Additionally, MPEP § 2173.05(g), Functional Limitations, states that “[i]f a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Accordingly, the rejection of claims 1 and 13-15 is maintained.

***New Objections, Necessitated by Amendment***

### ***Claim Objections***

12. Claim 3 is objected to because of the following informalities: although the substance of the claim has not been amended, it appears that in this latest claim listing, a space between the words “is” and “ANF” was omitted. A space between the words is therefore required.

### ***Conclusion***

13. No claims are allowed.

14. It is noted that since this application has an earlier effective filing date than co-pending application no. 12/905,773, and because the only remaining rejection of record for claims 2, 3, 16, and 64-68 is the provisional obviousness-type double patenting rejection, the claims would otherwise be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. In a phone interview with Applicant's representative, Anita Nador, on July 26, 2011, the following amendments to the claims were proposed for an examiner's amendment:

In claim **1**, lines 2-3, delete the words “any amino acid expect cysteine” and insert --- I or F --- therefore.

Cancel claim **2**.

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In claim **3**, line 1, insert a space in the word “isANF” so as to read “is ANF”.

Cancel claims **16**, **65** and **66**.

However, Applicant declined to pursue the suggested Examiner's amendment at this time.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is (571)272-2150. The examiner can normally be reached on Monday-Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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